BWC/MSP/2018/MX.2/WP.1

18 July 2018

English only

Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

2018 Meeting
Geneva, 4-7 December 2018

Meeting of Experts on Review of developments in the field of science and technology related to the Convention
Geneva, 9-10 August 2018
Item 6 of the provisional agenda
Development of a voluntary model code of conduct for biological scientists and all relevant personnel, and biosecurity education, by drawing on the work already done on this issue in the context of the Convention, adaptable to national requirements

Germany's best practice in handling (bio)security-relevant research: Self-governance organized by the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG)

Submitted by Germany

1. Scientific research plays a fundamental role in ensuring progress. Scientific freedom, which is enshrined in the German Basic Law, is a fundamental requirement in this respect. Yet free research is also associated with risks which result primarily from the danger of useful research findings being misused, for example as weapons of war and means of criminal or terrorist activities.

2. In the opinion of the German National Academy of Sciences Leopoldina and the German Research Foundation (DFG), legal provisions offer only a very limited means of controlling the opportunities and risks associated with free research. Research methods and content are constantly changing and research findings, as well as their future application, tend to be almost impossible to predict. The Leopoldina and the DFG continuously work to ensure that ethical principles and mechanisms for the responsible handling of free research and research risks are developed in science. As a response to the gain-of-function debate, in 2013, the DFG updated its "Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins" (see Annex) which is still valid today with the new scientific methods and opportunities of genome editing and of synthetic biology.

3. Moreover, in 2014, the DFG and Leopoldina published a set of general guidelines on handling security-relevant scientific research under the title "Scientific Freedom and

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Scientific Responsibility – Recommendations for Handling Security-Relevant Research".[1] This document places great importance on instruments of self-governance within the scientific community. The advantage of self-governance lies in researchers' high level of familiarity with the given subject and the fact that it allows for a flexible response. The recommendations are intended as an aid for researchers as well as a blueprint for research institutions implementing the corresponding regulations. They are aimed primarily at the government-funded research sector. However, their principles can certainly also be applied in the private sector.

4. In order to support German research institutions in the sustainable implementation of the Recommendations for Handling Security-Relevant Research, Leopoldina and DFG established the Joint Committee on the Handling of Security-Relevant Research. The Joint Committee consists of 12 scientific experts in relevant disciplines – from natural and life sciences to IT science, engineering, ethics and jurisprudence. The two chairpersons of the Joint Committee are a named representative of the Leopoldina Presidium and the Vice-President of the DFG.

5. The Joint Committee stays abreast of the progress in enacting the Recommendation on Handling Security-Relevant Research through monitoring and provides support to the research institutes for the implementation of the recommendations. Furthermore, the Joint Committee serves as a contact point for questions and a platform for the bundled exchange of information. Therefore, already more than 120 contact persons for handling security-relevant research have registered on the Joint Committee's website.[2] If it is not possible for an adequate decision about a particular case to be made locally, the Leopoldina may appoint ad-hoc working groups that, in close cooperation with the Joint Committee, can make a risk-benefit assessment of the research project in question.

6. In line with recommendations of DFG and Leopoldina, already more than 70 local committees for ethics in security-relevant research have been established throughout Germany. These committees enable the individual institutes to properly and responsibly deal with troubling issues arising from specific research projects and to decide themselves how to continue. By supporting the responsible self-governance of the scientific community, these mostly advisory bodies may also act as a means to strengthen compliance with the BWTC.

[1] Available at: www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf

[2] Available at: www.leopoldina.org/nc/en/about-us/cooperations/joint-committee-dual-use/list-of-committees

Annex

Code of Conduct: Working with Highly Pathogenic Microorganisms and Toxins

German Research Foundation (DFG) Senate Commission on Genetic Research (13 March 2013)

1. In recent years there has been rapid development in research in the field of infections, immunity and pathogenicity factors. The use of highly pathogenic microorganisms in research has yielded important scientific findings. The function of bacterial toxins, the entry and spread of highly pathogenic viruses in host cells and the relationship between cellular and humoral immunity and highly pathogenic microbes are all examples of areas of research that offer important potential for both basic research and the development of new diagnostic methods, treatments and vaccines.

2. However, the use of highly pathogenic microorganisms and toxins comes with the risk that research findings could be used to develop biological weapons. This is referred to as the 'dual use problem', and it is not limited to research involving highly pathogenic microorganisms and toxins. Examples of findings which are affected by this problem can also be found in other fields, such as materials science, computer science and even the social sciences. There exists a consensus that public safety should be considered the highest priority. However, we must also consider the benefits to human health that can be achieved through research with pathogenic organisms, as well as freedom of research and freedom of publication.

3. The Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) has discussed the dual use problem on many occasions in its statutory bodies. The DFG wants to provide researchers with a code of conduct which addresses the problems of working with highly pathogenic microorganisms and toxins and responds to the specific situation in Germany. The DFG has therefore drawn up the following recommendations for researchers working with highly pathogenic microorganisms and toxins:

(a) The DFG agrees with the decision of the National Research Council of the National Academies in the USA, which believes the following experiments to be particularly relevant to the dual use problem:

- Efforts to increase the virulence of pathogenic microorganisms or to convert apathogenic microbes into pathogenic microbes
- Experiments to induce resistance to effective antibiotics and antiviral substances
- Experiments to increase the transmissibility of pathogens
- Experiments to modify the host spectrum and stability of pathogens
- Efforts to avoid methods of diagnosis and detection
- Efforts to disclose the ineffectiveness of vaccines
- Experiments to make biological agents or toxins more suitable for use as weapons (weaponisation)

(b) The DFG believes it is necessary to carry out research work with pathogenic microorganisms and toxins. This is the only way in which we can develop strategies to combat dangerous pathogens and protect the population against infections. In addition,

many findings in basic research have been the result of work involving highly pathogenic microorganisms and toxins. The DFG therefore believes that as few restrictions as possible should be imposed on research involving pathogenic microorganisms.

(c) However, the DFG also promotes a responsible approach to work of this type. It expects researchers to evaluate their experiments at the planning stage and before starting work with regard to a potential dual use problem and to document this evaluation process in the laboratory records. This applies to the experiments themselves and to planned publications.

(d) The DFG will continue to fund research which addresses problems relating to highly pathogenic microorganisms and toxins. However, principal investigators should address an existing or potential dual use problem in their proposals. Reviewers are requested to assess the information provided by applicants and make a recommendation to the review boards.

(e) In the case of proposals where the dual use problem is applicable, the review boards will if necessary following preparation in an ad hoc working group carefully examine the proposals and, if appropriate, make suggestions as to how the proposed work should be carried out. If necessary, the responsible Senate Commission and/or the Senate may be involved in the process.

(f) The DFG does not believe that preventing the publication of sensitive findings is an effective way of minimising misuse. It believes that researchers must be allowed to continue publishing data relating to highly pathogenic microorganisms and toxins in peerreviewed journals. The publication of research data is a central requirement for scholarly self-evaluation. Only known dangers can be countered. The specific publication guidelines of the journals in question should always be observed.

(g) The DFG believes it is necessary to continue funding international cooperation, academic exchanges and the sharing of data, materials and methods in relation to research on pathogenic microorganisms and toxins. The appropriate national and international laws and guidelines must of course be observed.

(h) The DFG suggests that universities and non-university institutions should regularly hold seminars and other events for students, doctoral researchers and postdoctoral researchers on the subject of working with highly pathogenic microorganisms and toxins. The annual briefings required by the Genetic Engineering Act also provide an opportunity to raise awareness of the dual use problem. Research Training Groups, graduate schools, Collaborative Research Centres, research centres and clusters of excellence in relevant disciplines also provide suitable opportunities.

(i) The DFG advocates the continued development of best practice in connection with highly pathogenic microorganisms and toxins and the ongoing adaptation of the scientific framework. Findings should be shared with other organisations within Germany and abroad, for example the Medical Research Council (MRC) and the Wellcome Trust in the UK and the American Society for Microbiology (ASM). Relevant specialist associations and scientific academies could also make important contributions to this process.